Docket No. 372179-338791
US Appln. No. 09/801,908

REMARKS

Claims 1, 2, 4-11, and 21-23 are currently pending in this application. Claims 3 and 13-18 have been canceled without prejudice. Claims 21-23 have been added. Claims 1 and 4-11 have been amended. No new matter has been added.

The following remarks put the pending claims in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims.

35 U.S.C. § 112, First Paragraph, Rejection

Claims 1-11 and 13-18 stand rejected under 35 U.S.C. 112, first paragraph for allegedly failing to comply with the written description requirement.

The Office alleges that the "claims contain subject matter that was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." The Office further alleges that this subject matter includes the "ketoprofen mixture being 'caffeine-free' or 'non-encapsulated'."

In the interest of expedited examination, Applicants choose to not argue the merits of the sufficient written description rejection for the limitation reciting the "caffeine-free" property of the ketoprofen solution. Instead, applicants have amended the claims to read "consisting essentially of" certain materials. This is in concordance with the Office's suggestion provided in the previous Office Action. Therefore, such an amendment does not create any further written description problems and does not require any further search or consideration.

Applicants traverse the allegation that there is insufficient written description for the "non-encapsulated" limitation. Throughout the specification and claims, Applicants have consistently described the invention as water-soluble or an aqueous solution. Further, in the "Background of the Invention" of the specification, Applicants described

pill forms of ketoprofen and have explained advantages of the present invention over pill forms.

> The ability to administer ketoprofen in a non-invasive manner allows for the treatment of large groups of animals and for easier long-term treatment of individual animals with chronic disease. This formulation should prove beneficial in any condition where acute or chronic inflammation is involved where a desire to not give injections or pastes or pills is beneficial. (emphasis added) See page 3, lines 7-11 of the specification.

Thus, Applicants have clearly provided support for administering a ketoprofen solution by a method that does not include pastes or pills. However, one of ordinary skill in the art would recognize that "pastes or pills" generally encompasses encapsulated forms such as gel capsules.

Further, the last paragraph of the Background section describes the need that the invention meets. "There is a need for stable liquid forms of ketoprofen that can be orally administered (i.e., ingested) via an animals drinking water without rejection by the animal because of the bad taste imparted by the liquid ketoprofen" (see page 4, lines 7-9). Further, examples are given wherein the ketoprofen is administered via the animals' drinking water (see page 5, lines 8-19). This clearly conveys to one of ordinary skill in the art that the ketoprofen is to be provided to the animal in a non-encapsulated form.

The Board of Patent Appeals & Interferences (hereinafter "the Board") has held that negative limitations do not require literal support in the specification to satisfy the written description requirement. See *Ex parte Parks*, 30 USPQ2d 1234. The Board stated

> ...it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter....Clearly the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112.

Note that the instant case is similar to that decided by the Board in *Parks*. In *Parks*, the question before the Board was whether there was sufficient support for the limitation "in the absence of a catalyst" in a reaction step of a method claim. That is, in Parks and in the instant case, there are only two possibilities; in the presence of a catalyst or in the absence of a catalyst, and encapsulated or non-encapsulated, respectively. Thus, the instant case distinguishes from *Ex parte Grasselli, et al.*, 231 USPQ 393. In *Grasselli*, the Board held that there was not sufficient written description for negative limitations excluding certain elements from a catalyst. The Board stated "the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded." In the instant case, the only element that is included by the express exclusion of encapsulated forms is non-encapsulated forms.

Accordingly, Applicants respectfully suggest that there is proper written description for the limitation "wherein said solution is administered to said animal in a non-encapsulated form" present in all of the claims. Therefore, Applicants respectfully request withdrawal of the rejection based on 35 U.S.C 112, first paragraph.

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CONCLUSION

Applicants believe this response to be a full and complete response to the Final Office Action. In view of the foregoing, Applicants respectfully request reconsideration and allowance of new claims 1, 2, 4-11, and 21-23. As the application is believed to be in condition for allowance, Applicants respectfully request a Notice of Allowability. The Examiner is invited to contact the undersigned representative should any further issues arise

Respectfully submitted,

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